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REMARKS

Applicant has amended Claims 1, 21, 22, 30, and 34 to 39, as suggested by the Examiner, to place them in condition for allowance.

In addition, applicant has added Claims 43 to 45.

As requested by the Examiner, applicant has submitted four disclaimers for the following U.S. patents:

1) 6,177,077

2) 6,015,557

3) 6,419,934

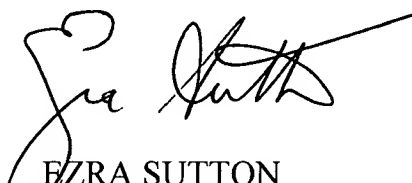
4) 6,419,944.

Applicant has also included a check for the four disclaimers.

It is believed that this application is in condition for allowance.

Respectfully submitted,

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REVISED VERSION OF CLAIMS

C1 1(amended). A method of treating neurological conditions in a human by inhibiting the action of TNF, by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of a fusion protein identified as etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I, and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose either intralesionally or perilesionally.

C2 ¹⁸~~21~~(amended). A method of treating or preventing nerve root injury in a human by inhibiting the action of TNF, by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

C2
amended

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I, and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose either intralesionally or perilesionally.

19
22(amended). A method of treating glaucoma in a human by inhibiting the action of TNF, by administering a TNF antagonist for reducing the inflammation of the optic nerve or retina of said human, or for modulating the immune response affecting the optic nerve or retina of said human, comprising the step of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I, and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for treating glaucoma by reducing the inflammation of the optic nerve or retina of said human, or for modulating the immune response affecting the optic nerve or retina of said human.

C3
~~21~~ 30(amended). A method of treating neurological conditions in a human by inhibiting the action of TNF, by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human, comprising the step of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of a fusion protein identified as etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I, and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human.

C4
~~25~~ 34(amended). A method of treating or preventing nerve root injury in a human by inhibiting the action of TNF, by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of a soluble TNF receptor Type I for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

C4
Amended

²⁶
~~35~~(amended). A method of treating or preventing nerve root injury in a human by inhibiting the action of TNF, by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of a pegylated soluble TNF receptor Type I for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

²⁷
~~36~~(amended). A method of treating or preventing nerve root injury in a human by inhibiting the action of TNF, by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the

immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of a molecule containing at least one soluble TNF receptor for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

28
37 (amended). A method of treating or preventing nerve root injury in a human by inhibiting the action of TNF, by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist consisting of a molecule which contains a fragment of any of the molecules selected from the group consisting of etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I,

and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose either intralesionally or perilesionally.

C4
Amended 29
38(amended). A method of treating or preventing nerve root injury caused by a herniated nucleus pulposus in a human by inhibiting the action of TNF, by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), a molecule containing a soluble TNF receptor, a molecule containing multiple soluble TNF receptors, and a molecule which contains a fragment of any of the above molecules for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose either intralesionally or perilesionally.

30
~~39~~

(amended). A method of treating a pathologic condition in a human by inhibiting the action of TNF, the pathologic condition being spinal cord compression due to metastatic cancer, by administering a TNF antagonist, defined as any of the following types of molecules directed against said TNF: a monoclonal antibody; a monoclonal antibody fragment; a TNF binding protein; or a fusion protein; comprising the steps of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist; and

b) administering said dose either intralesionally or perilesionally.
